

REMARKS

Applicants submit the within Amendment in response to the Official Action mailed May 20, 2004. The present communication is also intended as a record of the telephone interview between undersigned counsel and Examiner Stewart on September 24, 2004. The Examiner's courtesy in granting and conducting such interview is greatly appreciated. A petition for a two-month extension of time in which to respond is transmitted herewith. Reconsideration and withdrawal of the rejection of all the claims now in the application (*i.e.* claims 21-58) are respectfully requested.

Initially, the Examiner objects to the specification as failing to provide proper antecedent basis for the claimed subject matter. Specifically, the Examiner contends that the Applicants have not disclosed an "endless groove" and "an inner surface which extends perpendicularly to the longitudinal axis of the implant." While Applicants disagree with the Examiner's contention because, as quoted in MPEP § 2163, in *Vas-Cath*, the Federal Circuit held that "under proper circumstances, drawings alone may provide a 'written description' of an invention as required by § 112." 935 F.2d 1555, 1565, USPQ2d 1111, 1118 (Fed. Cir. 1991). However, to further prosecution, Applicants have deleted the terms from the pending claims, thus rendering the objection moot. Likewise, the objection to the drawings is also rendered moot.

The Examiner maintains his rejection of the claims under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,571,192 to *Schönhöffer* ("*Schönhöffer* '192"). The Examiner contends that *Schönhöffer* '192 discloses a fusion implant comprising an implant member (2) having a first end, a second end and an outer wall (3) defining an internal cavity. The

Examiner also contends that the valleys of the threaded surface on the outer wall can be interpreted as a plurality of grooves which encircle the whole circumference of the outer wall and segment the implant member into a plurality of ring-like segments. Each ring-like segment, the Examiner further contends, includes a plurality of apertures (9 & 10) extending in communication with the internal cavity. The Examiner also asserts that the *Schönhöffer* '192 implant includes a plurality of end caps (1 & 1'). The Examiner further asserts that claims 23, 24, 26, 27, 29, 36, 41 and 42 are anticipated as set forth on pages 3 and 4 of the Official Action.

Applicants respectfully traverse the rejection. As Applicants' undersigned counsel discussed with the Examiner during the September 24, 2004 telephone interview, the implant member (2) of *Schönhöffer* '192 plainly includes and requires "screw threads" rather than the discrete grooves of the claimed invention. As such, *Schönhöffer* '192's threaded grooves do not and cannot segment the implant member into discrete ring-like segments as shown in FIG. 1, as described in page 7 of the specification, and as required by the pending claims. Instead, the "screw threads" of *Schönhöffer* '192, which consist of continuous grooves beginning at each end of the implant and ending at the center region (8), segment the implant into *spiral* or *ribbon-like* structures. For this reason alone, *Schönhöffer* '192 cannot anticipate independent claims 21, 41, and 46, nor any of dependent claims 23-29, 35, 36, 42, and 43. However, to further prosecution, Applicants have amended independent claims 21 and 41 through a cite that none of the apertures and any of the at least one groove intersect each other. As is shown in FIG. 2 of *Schönhöffer*, it is plain that the screw threads intersect the apertures and therefore cannot anticipate the claimed invention.

In addition to the reasons set forth above, Applicants note the following with respect to claims 23, 26, 36 and 41-43. Regarding claim 23, the grooves of *Schönhöffer* '192 are not cutting guides and cannot act as cutting guides. As discussed above, the grooves of *Schönhöffer* '192 are screw threads, which are not designed or intended to be cut by the surgeon. Were a surgeon to use the threads as a cutting guide to size the implant, the surgeon would end up cutting the implant member into a helical or spiral-shaped structure, unlike the ring-like segments produced by using the grooves of the claimed invention as a cutting guide to size the implant member. In this regard, Applicants have amended claim 23 to more clearly recite that the groove acts as a cutting guide to determine the desired length of the fusion implant.

Regarding claim 26, which recites that the height of at least two of the ring-like segments are varied, Applicants note that because *Schönhöffer* '192 discloses a threaded groove that begins at one end of the implant and ends at the center section (8), discrete ring-like segments are not produced. Again, should a surgeon cut along the threaded groove, one would not produce ring-like segments of varying height but would instead produce a helical structure.

Further, with respect to claim 36, Applicants submit that one of ordinary skill in the art would not equate the locking pins of the present invention with the plurality of peaks created by the threaded bore in each cap of *Schönhöffer* '192. The threaded bore in each cap of *Schönhöffer* '192 is actually one continuous thread extending in a helical fashion along the end cap and, as such, cannot be interpreted as a plurality of locking pins. As one of ordinary skill in the art would recognize, the threaded bore of *Schönhöffer* '192 functions by screwing the end cap to the outer wall of the implant member, rather than snapping the threaded bore onto the implant member.

As such, the threaded bore of the *Schönhöffer* '192 patent is significantly different from the locking pins of Applicants' invention.

With respect to claims 41-43, Applicants again note that the claimed method includes providing an implant member having at least one groove which encircles the outer wall and segments the implant member into discrete ring-like segments. As noted above, the screw threads of *Schönhöffer* '192 do not segment the implant member into discrete ring-like segments, but rather segment the implant member into helical or spiral structures. Moreover, as noted by the Examiner, the length of the implant of *Schönhöffer* '192 is increased (or decreased) by rotating the center element (2) in order to force out (or in) the end elements and bring their outer ends at a certain length. This is plainly different from the sizing of the implant member in the claimed method, wherein the length of the implant member is shortened by separating one or more of the ring-like segments at a selected groove. As such, *Schönhöffer* '192 cannot anticipate the cited claims.

On page 5 of the Official Action, the Examiner has rejected claims 21-30, 35, 36 and 41-52 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,558,423 to *Michelson* ("*Michelson*"). The Examiner contends that *Michelson* discloses a fusion implant comprising an implant member (100), the implant member having a first end, a second end, and an outer wall defining an internal cavity. The Examiner also contends that the outer wall has a plurality of grooves, which encircle the whole circumference of the outer wall and segment the implant member into a plurality of ring-like segments. The Examiner further contends that each ring-like segment includes a plurality of apertures extending in communication with the internal cavity, and that the second end of the implant member is a mechanical connection to a cap. With respect to claim 23,

the Examiner asserts that the grooves are capable of acting as a cutting guide. With respect to claim 24, the Examiner also asserts that the grooves are capable of acting as a measurement guide, for example, upon measuring the separation between one groove and the collar and/or the thickened center region the surgeon is capable of determining an exact length. Finally, the Examiner has rejected claims 26, 27, 29, 36, 41, 44 and 47-52 as set forth on pages 5 and 6 of the Official Action.

As noted above, Applicants have amended the claims to recite that the grooves do not intersect the apertures of the fusion implant. This is in contrast to Fig. 1 of *Michelson*, which plainly shows that opening 134 intersects what the Examiner has interpreted as grooves. As such, *Michelson* cannot anticipate independent claim 21 nor dependent claims 23-30, 35, and 36.

With respect to pending claims 41-43, *Michelson* does not teach a fusion implant of adjustable lengths and therefore cannot anticipate the claimed method, which requires sizing of the implant member.

With respect to claim 46, which has been amended to require that the implant member has a plurality of grooves which encircle the outer wall and segment the implant member into discrete ring-like segments wherein none of the grooves intersect the apertures, the alleged grooves of *Michelson* plainly intersect opening 134 of Fig. 1.

The Examiner has also maintained his rejection of claims 31-33 under 35 U.S.C. § 103(a) as being obvious over *Schönhöffer* '192 in view of U.S. Patent No. 6,015,436 to *Schönhöffer* ("*Schönhöffer* '436"). While the Examiner recognizes that *Schönhöffer* '192 does not disclose a plurality of spikes arranged radially about the face of the end caps, the Examiner relies upon *Schönhöffer* '436 as teaching an implantable disk prosthesis comprising implant member (1) having a first end and

a second end having a plurality of spikes (12) radially about the face of the first and second ends for the purpose of having a good attachment with the walls of the vertebrae (citing col. 4, lns. 13-24). The Examiner concludes, therefore, that it would have been obvious to modify the distal ends of the *Schönhöffer* '192 implant with the distal end spikes of the *Schönhöffer* '436 in order to have a good attachment with the walls of the vertebrae.

Applicants respectfully traverse the rejection. As noted above, *Schönhöffer* '192 teaches an implant member having screw threads that cannot segment the implant member into discrete ring-like segments, as required by dependent claims 31-33. In addition, *Schönhöffer* '192 does not teach an implant member wherein the apertures and the grooves do not intersect each other. As such, claims 31-33 cannot be obvious over *Schönhöffer* '192 in view of *Schönhöffer* '436.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone Applicants' attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge

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Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

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